



WISCONSIN REGULATORY DIGEST

Volume 11, No. 2

A Publication of the
PHARMACY EXAMINING BOARD

September, 1999

Department Overview

by Secretary Marlene A. Cummings

As Secretary of the Wisconsin Department of Regulation and Licensing, I am frequently asked for information about the department and believe that it is useful from time to time to discuss the structure and philosophy which guides the work of this department as well as providing information of the department's current strategic business goals.

The Department of Regulation and Licensing is an umbrella agency, which provides services to over 20 boards. These boards are responsible for the regulation of a wide variety of professions and the department independently regulates many other

professions, occupations and entities. There are basically three different regulatory activities provided by the boards and the department. They are: 1) the application and examination process; 2) defining what the credentials entitles the credential holder to do through scope of practice; professional conduct and professional ethics written into administrative code, and; 3) enforcement.

One of the more unique oversight board arrangements in the department is the joint board which regulates professional engineering, architects, landscape architects, designers and land surveyors. This joint board is in the Division of Business Licensure and Regulation. The division is divided into two bureaus to allow for more direct service staff to become better acquainted with the issues surrounding each profession.

This board, along with all other boards in the department, set standards of professional competence and conduct for the profession under its charge; prepares, conducts and grades the examinations of prospective new practitioners; grants licenses; investigates complaints of alleged unprofessional conduct; and performs other functions assigned to it by law. One of the most important departmental responsibilities is to assist the boards in discharging these duties.

THE WISCONSIN PHARMACY EXAMINING BOARD

Members of the Board:

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Administrative Staff:

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Marlene A. Cummings, Secretary
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In addition the department also:

- * Acts as a conduit for professions and their interaction with other state agencies or the governor's office.
- * Has broadened its enforcement authority to respond more effectively and efficiently to complaints of unlicensed practice. Through the administrative injunction process, the department is able to effectively enforce licensure requirements.
- * Is in the process of using new technology to upgrade our services to customers through expanded use of automated telecommunications services and by facilitating electronic transmission of information via the internet.
- * Is exploring more opportunities for seminars and information exchanges with professional credential holders and their statewide associations to learn more about the professions and how we can provide better services.

Y2K Update

By the end of this year, everyone - no doubt - will be tired of hearing about the Y2K "problem." The issue has received, and will continue to receive, considerable attention in the media and workplace. Governor Tommy Thompson has made Y2K readiness one of the top priorities of his administration and is committed to ensuring that state agencies are ready to deal with any and all problems which may result from the coming of the year 2000.

The Department of Regulation and Licensing, like all other state agencies, has been preparing for the last couple of years now for the switch to the year 2000. We have analyzed major functions in the department and have identified areas where work was needed in order to prepare for a smooth transition to the year 2000. We are confident that our preparations are on track and we anticipate no major problems in the department as we approach the year 2000.

There are three main areas which can summarize our progress towards dealing with Y2K issues. They are:

Applications: All of our applications have been converted over to the Oracle database and these processes are Y2K compliant.

Hardware and System Software: The department is currently in the process of upgrading all of our personal computers to ensure that they are Y2K compliant. A complete department-wide testing of all computer hardware devices is being planned for July, 1999.

Contingency Plans: The department is also developing a contingency plan to address issues related to business resumption in case a disaster involving unforeseen problems may arise due to Y2K issues.

We are confident that our actions to date and the additional efforts which will unfold over coming months will ensure that the department will see a smooth transition from 1999 to 2000. We will keep you posted on an "as needed" basis should other issues materialize or if we need to provide any additional information regarding departmental goals and actions which are aimed at successfully managing the Y2K issue.

Division of Enforcement

A critically important component of the role played by the Department of Regulation and Licensing (DORL) in overseeing professions subject to licensure and regulation is the Division of Enforcement (DOE), headed by Jack Temby.

The DOE is a large division comprised of attorneys, investigators and support staff. Their primary mission is to conduct investigations of complaints received by the department concerning the conduct of persons holding professional credentials or licenses issued by the department. In the most recently completed biennium (1995-97) more than 4,400 complaints were received and processed by the division. When appropriate, complaints are resolved through mediation. However, if it appears there has been a violation of the laws enforced by the boards or department, formal disciplinary action may be commenced against the credential holder involved.

There are four distinct phases of the case handling process and are as follows:

- * **Intake Stage:** This is the first stage in the case handling process. Cases are screened by screening panels to determine if an investigation is warranted. Cases that do not warrant investigation are quickly closed. Cases that appear to have merit are identified for investigative action.
- * **Investigation Stage:** This is the next stage in the case handling process. Investigative staff gather necessary evidence and make contacts with witnesses as needed. The results of the investigation are discussed with a case advisor and a department attorney. Cases that do not warrant professional discipline are closed. Cases with violations proceed to the next stage for legal action.

- * **Legal Action Stage:** In this stage, department prosecuting attorneys, in conjunction with case advisors, review the results of the investigation and pursue disciplinary action when appropriate. Cases may resolve by means of stipulated agreements, informal settlement conferences or letters of concern.
- * **Hearing Stage:** The last stage is the hearing Stage. This is a formal legal process. The department attorney litigates the case before an administrative law judge. The law judge makes a proposed decision which is reviewed by the licensing board. If a violation is found, discipline may be imposed. Disciplines include reprimand, limitation, suspension and revocation.

To file a complaint you may contact the Division of Enforcement by calling (608) 266-7482 or (608) 266-3736, or write the Department of Regulation and Licensing, Division of Enforcement, P.O. Box 8935, Madison, WI 53708-8935.

Continuing Education Requirement

All pharmacists must complete 30 hours by June 1, 2000

Each pharmacist is required to complete this continuing education requirement and sign a statement on their application for renewal on June 1, 2000 certifying that they have completed at least 30 hours of continuing education offered by ACPE (American Council on Pharmaceutical Education) approved providers within the 2-year period immediately preceding June 1, 2000. This does not apply to an applicant for renewal of a license that expires on the first renewal date after the date on which the Board initially granted the license.

While under current rules the Board has the authority to also approve individual courses offered by providers other than those by ACPE approved providers, the Board has not nor does not intend to approve any such course prior to June 1, 2000 at the time of this writing.

The Board has approved an equivalency ratio to allow licensees enrolled for credit in post graduate pharmacy education to count each credit earned during the two years prior to relicensure application to count the same as 10 credits of coursework offered by an ACPE approved provider. Documentation of this education must be retained as described herein.

A pharmacist may apply to the Board for waiver of this requirement on grounds of exceptional circumstances such as prolonged illness, disability or other similar circumstances that the pharmacist

indicates have prevented him or her from meeting the requirement. The Board will consider each application for waiver individually on its merits.

Each pharmacist shall retain evidence of compliance with this continuing education requirement for 3 years following the renewal date for the biennium for which 30 hours of credit are required for renewal of a license. For example, a pharmacist who renews his or her license on June 1, 2000 must retain proof of having obtained 30 hours of continuing education in the two years preceding renewal until June 1, 2003. The Board may require any pharmacist to submit his or her evidence of compliance with the continuing education requirement to audit compliance. The Board will accept either original documents or verified copies as evidence of compliance.

Technician Issues

"It is the position of the Pharmacy Examining Board (PEB) that the addition of a diluent to a prefabricated dosage form exactly as instructed on the manufacturer's label can be done by an agent of the pharmacist so long as the pharmacist verifies the accuracy of the agent's action." We hope that the above stated position clarifies the particular issue of reconstituting antibiotics plus allowing broader interpretation for other similarly manufactured products.

The Board has received several letters from pharmacy technicians concerning the reconstituting of antibiotics. Board members are concerned the technicians did not appreciate while the task itself might be viewed as a simple one, the responsibility of such tasks is great. The responsibility for all patient outcomes resulting from such tasks resides solely on the pharmacist that delegated the task. Pharmacists are strongly advised to communicate with their technicians that any task, if done incorrect, can result in a serious dispensing error and harm to a patient. The PEB is currently working on changes to Phar 7 that will define a pharmacy technician and will clarify what may and may not be delegated by a pharmacist to that technician.

Pharmacists are reminded that to abide by the 2:1 technicians to pharmacist ratio the pharmacist must also include any employee that is prepacking medications. This technician is performing an aspect of the dispensing function that requires a pharmacist to check its accuracy and correctness.

Personnel in a Closed Pharmacy

It is the opinion of the PEB that other personnel (bookkeeper, cleaner, etc) may be working in a closed pharmacy in the absence of a pharmacist as

long as they are not doing delegated pharmacist functions (technician functions). The managing pharmacist is ultimately responsible for the security of a pharmacy.

Complaints Against Out-Of-State Pharmacies

Currently, Wisconsin State Statutes do not allow the Board of Pharmacy to regulate out-of-state pharmacies. The Board conducted a survey through NABP (National Boards of Pharmacy) asking other boards about their regulation of out-of-state pharmacies. Many of the boards indicated that even when they had the authority to investigate they chose to send the information they gathered on a case to the state board in the state that the pharmacy was located. The Department of Regulation and Licensing's Division of Enforcement staff has been instructed by the PEB to send forms to all persons having a complaint about a pharmacy or pharmacist, regardless of whether they are licensed by this state. The Board will then review and forward the complaint to the appropriate state board. Pharmacists are encouraged to use this avenue to inform the PEB of possible violations of law in the state where the pharmacy is licensed. This would also include information concerning situations where persons are accessing prescription drugs without a legal prescription through the Internet.

Medical Examining Board Anorectic Drugs

MED 10.02 (2)(zb) has been added by the Medical Examining Board to expand the definition of unprofessional conduct for a physician to include the prescribing of controlled substances for the purpose of weight reduction unless they meet the following specific conditions. A physician that issues a prescription that does not meet these conditions is not to be considered a legitimate prescription within the meaning and intent of ss. 450.01(21) and 961.38, Stats. The person **knowingly dispensing** pursuant to such a purported order, as well as the person issuing it, shall be subject to the penalties provided for violation of the **provision of law relating to controlled substances as well as constituting unprofessional conduct.**

Med 10.02 (2) The term "unprofessional conduct" is defined to mean and include..... (zb) Prescribing, ordering, dispensing, administering, supplying, selling or giving any anorectic drug designated as a schedule II, III, IV or V controlled substance for the purpose of weight reduction or control in the treatment of obesity unless each of the following conditions is met:

1. The patient's body mass index, weight in kilograms divided by height in meters squared, is greater than 25.

2. A comprehensive history, physical examination, and interpreted electrocardiogram are performed and recorded at the time of initiation of treatment for obesity by the prescribing physician.
3. A diet and exercise program for weight loss is prescribed and recorded.
4. The patient is weighed at least once a month, at which time a recording is made of blood pressure, pulse, and any other tests as may be necessary for monitoring potential adverse effects of drug therapy.
5. No more than a 30-day supply of drugs is prescribed or dispensed at any one time.
6. No drugs are prescribed or dispensed for more than 90 days unless all of the following occur:
 - a. The patient has a recorded weight loss of at least 12 pounds in the first 90 days of therapy.
 - b. The patient has continued progress toward achieving or maintaining a target weight.
 - c. The patient has no significant adverse effects from the prescribed program.
7. Any variance from the foregoing requirements is justified by documentation in the patient's record.

Duty to Report

In its role as a protector of the citizens of Wisconsin, the PEB depends on its pharmacist licensees to self-monitor the professional practices of all their fellow Wisconsin pharmacists. The PEB keeps such reporting as confidential as possible.

Phar 10.03 (7) states that it is unprofessional conduct to fail to report to the PEB any pharmacy practice which constitutes a danger to the health, safety or welfare of patient or public. This rule includes pharmacists that have knowledge of a pharmacist that is practicing while impaired by alcohol or drugs. As difficult as reporting a colleague may be, it is necessary to require this to protect the public safety. Failure to report this type of practice has resulted in PEB action against the "non-reporting" pharmacists.

Administrative Warnings

As of February 1, 1999, the Pharmacy Examining Board may issue an administrative warning to close an investigation if no further action is warranted because the complaint involves a first occurrence of

a minor violation and the warning adequately protects the public.

Under the law, the administrative warning puts the pharmacist on notice that if the misconduct is repeated, the incident that was the basis for the warning can be used to prove that the pharmacist warned knew the conduct was prohibited. A warning is not considered discipline and may be issued without a formal hearing. The contents of a warning are confidential and thus will not be published in the Regulatory Digest. The Board plans to publish general descriptions of the types of cases that resulted in administrative warnings for pharmacists. This will assist in understanding the standard of practice the Board expects of Wisconsin pharmacists.

Reminder Alarm System Required

Effective January 1, 2000, a pharmacy shall have a centrally monitored alarm system in the pharmacy or the immediate physical structure within which the pharmacy is located.

Did You Know.....

In 1998, 116 pharmacists reciprocated their license into Wisconsin and 52 pharmacists requested licensure transfer out of the state.

As of May 1999, the PEB voted to eliminate the "wet lab" (compounding) examination as a requirement for licensure in Wisconsin. An Exam Task Force is reviewing the entire examination process and content for possible future changes.

That in August, 1998, 83% of candidates passed the Wisconsin compounding/consultation exam and that in June, 1999, 93% of candidates passed the Wisconsin consultation exam.

The PEB is working on changing the rule that limits prescription transfers between pharmacies.

The FDA is replacing the former legend statement (Caution: Federal law prohibits dispensing without prescription) with the symbol "Rx only" on the label of prescription products.

Disciplines

KAREN LOEB, R.PH.

BROOKFIELD WI REPRIMAND/\$250 COSTS
Failed to detect that technicians had prepared a package for a patient selecting the wrong dosage of Coumadin. Effective 2/9/99. Sec. 450.10(1)(a)6., Stats. Phar 10.03(2) Case #LS9804091PHM

THOMAS P. ROSE, R.PH.

TOMAH WI REVOKED/STAYED/\$12,764.61
COSTS

Diverted and self-administered Demerol. Provided

false information to the board. Revoked; stayed with limitations. Effective 2/25/99. Sec. 450.10(1)(a)2.3., Stats. Phar 8.05(2), 10.03(1),(8) Case #LS9711181PHM

CRAIG R. OSNESS, R.PH.
MILWAUKEE WI

REPRIMAND/LIMITED/\$1,400
COSTS/\$2,000 FORFEITURE

In an audit of the pharmacy in which he was the managing pharmacist, approximately 58,000 dosage units of controlled substances were missing and could not be accounted for. Effective 3/10/99. Sec. 450.08(1), Stats. Phar 8.02(1) Case #LS9903102PHM

THEODORE S. REGALIA, R.PH.

BAYSIDE WI REPRIMAND/\$100.00 COSTS

As the immediate supervisor of the managing pharmacist, he observed the managing pharmacist to be impaired and did not report or inform the board of the pharmacist's apparent impairment. Effective 6/16/99. Phar 10.03(7) Case #LS9906164PHM

JEFFREY A. WEJROWSKI, R.PH.
MILWAUKEE WI

SUSPEND ONE YEAR/
LIMITED/\$1,900.00 COSTS

Convicted of felonies relating to medical assistance fraud and medical assistance prohibited conduct. Suspend 1 year effective 3/1/99. Limited effective 2/12/99. Secs. 49.49(1)(a)1., 450.10(1)(a)(2),(7), 943.20(1)(b), Stats. Case #LS9808312PHM

JEFFREY S. ANDERSON, R.Ph.
OAK PARK HEIGHTS MN

SUSPEND INDEFINITELY/
\$400.00 COSTS

Over a three year period diverted drugs from his place of employment for his personal use. All of his controlled substance use was without prescription or other authority. Suspended indefinitely; may apply for a stay. Effective 12/8/98. Secs. 450.10(1)(a)2, and 3., 450.11(7)(h), 940.20(1)(a), Stats. Phar 8.05(2), 10.03(1)(a) Case #LS9812082PHM

OSCO DISTRIBUTION CENTER
ELK GROVE VILLAGE IL

REPRIMAND/\$400.00 COSTS

Caused to be delivered to a number of Wisconsin prescribers approximately 10,000 prescription order blanks which were imprinted with the name and addresses of Osco pharmacies, pharmacies wholly owned by respondent's parent company, American Stores Company. Effective 1/13/99. Phar 10.03(15) Case #LS9901135PHM

PATRICIA HAMILL, R.PH.
DEHAVAN WI

REPRIMAND/\$450.00 COSTS

Was observed transferring a refill prescription to a patient without a consultation. Effective 3/10/99. Phar 7.01(1)(e) Case #LS9903103PHM

WILLIAM KARWOSKI, R.PH.
GREENFIELD WI

SUSPEND/STAYED/LIMITED/
\$200.00 COSTS

Took controlled substances without authority and without consent from his employer for his own consumption. Also practiced while these medications were in his body. Was convicted of felony obtaining a controlled substance by fraud. Effective 3/10/99. Secs. 450.10(1)(a)2., 3., 943.20(1)(a), 961.38(3), Stats. Phar 8.05(2), 10.03(1),(2) Case #LS9903105PHM

PATRICK W. FREY, R.PH.

BRYANT WI REPRIMAND/\$250.00 COSTS

Received a prescription from a physician for four syringes of morphine sulfate, a schedule II controlled substance, which identified the same prescribing physician as the patient. Effective 1/13/99 Phar 8.04, 10.03(1),(2) Case #LS9901133PHM

BECKY L. GOBERMANN, R.PH.

MADISON WI REPRIMAND/LIMITED/
\$150.00 COSTS

Disciplined in Illinois for obtaining prescription medications for herself beyond the refill authorizations of the prescriber on multiple occasions. Effective 1/13/99. Phar 10.03(17) Case #LS9901134PHM

GERALD D. HANCOCK, R.PH.

HAUPER PHARMACY
UNION GROVE WI

REPRIMAND/LIMITED/
\$1,000.00 FORFEITURE/
\$300.00 COSTS

Routinely allowed an unlicensed person to transfer a prescription to a patient without consultation. Effective 6/16/99. Phar 7.01(1)(e), 10.03(2),(3) Case #LS9906163PHM

RALPH G. KOCH, R.PH.
SHEBOYGAN WI

SUSPENDED/STAYED/
\$639.00 COSTS

Made a number of documented computer entry errors which he did not detect during the normal error-correcting process in place at the time, and which, if they had not been detected, could have

posed a risk to a patient. Effective 6/16/99. Sec. 450.10(1)(a)2.,3., 6., Stats. Phar 10.03(2) Case #LS9901061PHM

HOLLY M. SLUSSER, R.PH.

OREGON WI REPRIMAND/
\$150.00 COSTS/
\$500.00 FORFEITURE

Removed samples of prescription medications from a physician's supply for a friend without a physician's order and without consent of the physician. Effective 1/13/99. Sec. 450.10(1)(a)6., Stats. Phar 10.03(1)(2). Case #LS9902094PHM

KEVIN M. PAMPUCH, R.PH.

OAK CREEK, WI
SUSPEND/STAYED/LIMITED/
\$100.00 COSTS

Diverted controlled substances from place of employment for his own use. Was observed on a hidden camera putting the drugs in his hand. Convicted in circuit court of misdemeanor theft, obtaining a controlled substance by deceit. Effective 3/10/99. Secs. 450.10(1)(a)2.,3., 450.11(7)(h), 940.20(1)(a), Stats. Phar 8.05(2), 120.03(1),(2) Case #LS9903104PHM

CORY S. FORD, R.PH.

MUKWONAGO WI
SUSPEND/STAYED/LIMITED/
\$100.00 COSTS

After discharge from the Impaired Professionals Procedure, relapsed to the use of cocaine which he obtained from expired topical cocaine liquid containers from his employing pharmacy. Effective 3/10/99. Sec. 450.10(1)(a)2.,3., Stats. Case #LS9903101PHM

WILLIAM J. LEONARD, R.PH.

GREEN BAY WI
REPRIMAND/\$250.00
FORFEITURE/\$100.00 COSTS

Unlicensed person transferring prescriptions without consultation from a pharmacist. Effective 2/9/99. Phar 7.01(1)(e) Case #LS99020993PHM

RONALD J. COLLARD, R.PH.

APPLETON WI REPRIMAND/\$250.00
FORFEITURE/\$100.00 COSTS

Unlicensed person transferring prescriptions without consultation from a pharmacist. Effective 2/9/99. Phar 7.01(1)(e) Case #LS9902091PHM

JEAN M. FLESCH, R.PH.

APPLETON WI REPRIMAND/\$250.00
FORFEITURE/\$100.00 COSTS

Unlicensed person transferring prescriptions without consultation from a pharmacist. Effective 2/9/99. Phar 7.01(1)(e) Case #LS9902092PHM

GREGORY A. LINTON, R.PH.
RICE LAKE WI

REPRIMAND/\$450.00
COSTS/\$500.00 FORFEITURE

An individual called the pharmacy asking what information was required to accept payment from the Wisconsin HIV/AIDS Drug Reimbursement Program and in response the pharmacist disclosed a patient's name, his HIV status, that he was receiving medications and public assistance to help pay for his medications. The patient had not given consent for disclosure of that information. Effective 6/16/99. Phar 10.03(6) Case #LS9906162PHM

KEVIN T EGGENBERGER, R.PH.
WAUWATOSA WI

REPRIMAND/\$250.00
FORFEITURE/\$250.00 COSTS

Allowed an unlicensed person to transfer a new prescription to a new patient. Made an error in dispensing with no warnings about any side effects or drug interaction problems. Effective 11/10/98. Phar 7.01(1)(e), 10.0392) Case #LS9811101PHM

Telephones

Automated phone system for the Health Professions:
(608) 266-2811

Press 1 **Request Application**

Press 2 **Status of a Pending Application**

Press 3 **Complaint Filing Information**

Press 4 **Verifying Current Status of a
Credential Holder**

Press 5 **Name or Address Change**

Need a Duplicate License

Request a Letter of Good Standing

Press 6 **Repeat Menu Choices**

Fax Number

(608) 261-7083

All requests for verification of license status must be in writing. There is no charge for this service.

Endorsements

Requests for endorsements to other states must be in writing. The cost is \$10. Please make check or money order payable to the Department of Regulation and Licensing.

Digest on Web Site

March 1998, September 1998, April 1999

Visit the Department's Web Site

<http://badger.state.wi.us/agencies/drl/>

Send comments to dorl@drl.state.wi.us

1999 Board Meeting Dates

September 14, October 13, November 9,
December 7

Verifications

Department of Regulation and Licensing
Pharmacy Examining Board
P.O. Box 8935
Madison, WI 53708-8935

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Wisconsin Statutes and Code

Copies of the Pharmacy Examining Board Statutes and Administrative Code can be ordered from the Department. Include your name, address, county and a check payable to the Department of Regulation and Licensing in the amount of \$5.28. The latest edition is dated January, 1999.

Change of Name or Address?

Please photocopy the mailing label of this digest, make changes in name or address, and return it to the Department. Confirmation of changes are not automatically provided.

WIS. STATS. S. 440.11 ALLOWS FOR A \$50 PENALTY TO BE IMPOSED WHEN CHANGES ARE NOT REPORTED WITHIN 30 DAYS.

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